

SUBJECT:	Suspect/Counterfeit Items OQBP Procedure	NUMBER:	1006.1002
RESPONSIBILITY:	Office of Quality and Best Practices	REVISION:	001
APPROVED BY:	Head, Office of Quality and Best Practices	EFFECTIVE:	03/19/2010

QA

1006

Administrative Procedure

1002

Suspect/Counterfeit Items OQBP Procedure

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1.0 Purpose

The purpose of this procedure is to describe the activities of the Office of Quality and Best Practices (OQBP) as they relate to prohibiting or controlling the use of suspect/counterfeit items (S/CI) discovered at Fermilab.

2.0 Scope

All new and existing items, equipment, products or parts at Fermilab are within the scope of this document.

3.0 Applicability

This procedure applies to OQBP, Senior Safety Officers for divisions/sections/centers, the Fermilab site Safety Officer, the Fermilab Chief Operating Officer and division/section S/CI coordinators and other Fermilab personnel involved with the resolution of discovered S/CI.

4.0 Responsibilities

4.1 The Fermilab Director

- Approves the S/CI policy as part of Director's Policy #10, Quality Assurance
- Holds management accountable for implementation of, and compliance with, this program and its implementing procedures
- Appoints OQBP as the Fermilab site S/CI Coordinator

4.2 Heads of Divisions/Sections/Centers

- Ensure compliance with this procedure for their areas of responsibility including flow down of requirements and awareness
- Provide the necessary resources as appropriate to implement this procedure
- Ensure individuals within their division/section/center are trained in S/CI where required
- Appoint S/CI coordinators for each division/section/center

4.3 The Office of Quality and Best Practices

- Oversees the Fermilab S/CI Program and serves as the site S/CI Coordinator
- Provides support to line management and S/CI Coordinators in resolving open S/CI issues
- Recommends what notification to the DOE Office of the Inspector General and the DOE Site Office is required
- Forwards requests for subject matter expert (SME) guidance to the relevant laboratory ES&H subcommittee chairs when S/CI discoveries or reports require a laboratory response.
- Provides periodic status reports to the Fermilab Assurance Council, the Laboratory Director, responsible managers, and others as appropriate
- Maintains training materials and works with ES&H and D/S/C training to provide training

4.4 Employees, Subcontractors and Users

- Receive training in S/CI awareness as it pertains to their work
- Notify their immediate supervisor when a potential S/CI is discovered
- Follow applicable FESHM policies and procedures

4.5 Supervisors

- Notify appropriate line management and S/CI coordinator of potential S/CI
- Refer to 1006.1001 Controlling Suspect/Counterfeit Items Procedure when a potential S/CI is discovered

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- Determine training requirements
- Ensure that S/CI-related information is flowed down to all employees , subcontractors and users working under their direction as appropriate, either through formal training or transfer of information (with records maintained) by an S/CI-trained Fermilab employee

4.6 Division/Section/Center S/CI Coordinators

- Work with the supervisor, engineering, OQBP, Procurement, or other subject matter expert, to document and resolve reported S/CI
- Maintain an S/CI log

4.7 Senior Safety Officer for Division/Section/Center

- Respond to requests for safety related evaluation of S/CI
- Inform local S/CI Coordinator and OQBP when the result of a safety related evaluation of S/CI identifies a safety risk

4.8 Fermilab ES&H Committee (FESHCOM) Chair

- Bring requests from OQBP for SME guidance on S/CI to the relevant subcommittee for review and response
- Provide the laboratory's response to requested S/CI reviews
- Elevate to other ES&H subcommittees or the laboratory ES&H committee if necessary

4.9 Procurement

- Incorporate technical requirements that are a part of or attached to the relevant requisition into the subcontract
- Contact subcontractor and ensure that Fermilab's S/CI concern is documented in the subcontract file

5.0 OQBP Procedure for Resolving Identified S/CI

This section describes the step by step procedure followed by OQBP for resolving S/CI which are reported to the Office of Quality and Best Practices. (See the flowchart in appendix I).

5.1 A division/section/center S/CI coordinator notifies OQBP of potential S/CI identified and provides all available supporting materials including line management contact information, the S/CI report form, assigned S/CI tag identification and any information entered into an S/CI log. The S/CI coordinator also indicates if it was necessary to notify an SSO.

5.2 OQBP reviews the available information and confers with necessary personnel and provides any preliminary instructions necessary to prevent use of the S/CI until the S/CI is resolved.

5.3 OQBP determines whether an item is officially considered suspect for Fermilab.

5.3.1 When an item is deemed suspect OQBP:

- Ensures that the S/CI log contains the necessary updates
- Requests any additional information required from Procurement

Note: By definition, items deemed suspect by OQBP have already been confirmed as non-conforming to requirements specified in a purchase order

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- Initiates a request for a Corrective Action Plan (CAP) and/or a nonconforming / discrepant material report and ensures the supporting procedures are followed
- Determines if it is necessary to notify all division/section/center S/CI coordinators. When so notified and when the notice indicates “response required” S/CI coordinators are responsible to ensure that their division/section/center is inspected for the reported suspect item(s) and to follow the requirements specified in procedure 1006.1001, Controlling Suspect/Counterfeit Items Procedure.

Note: if the S/CI notice from OQBP does not indicate “response required”, then it is for awareness only and local management will determine if any action is required.

- Notifies Site DOE
- Determines if any ORPS reports were filed for the S/CI
 - IF no ORPS were filed, THEN confirms FESHM 3010 is followed as required
- Reviews the S/CI log for procurement history on the supplier of the suspect item(s)
- Recommends if notification to the DOE Office of the Inspector General is necessary.
 - IF necessary, THEN recommends notification to the COO who decides if notification is necessary and if so contacts IG and proceeds according to IG instructions

Note: IG makes the official determination whether an item is counterfeit and advises OQBP on any further actions to be taken by Fermilab

Note: In the event where IG advises Fermilab to destroy some or all of the suspect items, disposal must be done in a manner to prevent reuse and records of destruction must be provided to OQBP. On site destruction is the responsibility of line division/section/center line management. For offsite destruction, contact the Business Services Section, Property and Inventory Control Manager.

- Notifies Procurement of requirements to proceed
- Ensures that the S/CI reports and log are updated as necessary
- Ensures that other reports (such as CAR, NCR, ORPS, PAAA, CAIRS) are completed as applicable

5.3.2 IF an item is not deemed suspect, THEN OQBP determines if the S/CI requires further investigation

- The item is entered into the OQBP Issues Management System and issues are assigned to specified individuals with an IMS Corrective Action Request when necessary.
- OQBP determines if an item is to be released or other disposition.
- IF disposition requires destruction THEN OQBP receives records of destruction to ensure that reuse of S/CI is prevented.

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6.0 Records

S/CI Log

Records of destruction

7.0 Review Cycle

This procedure shall be reviewed for accuracy and relevance on at least a three year cycle

7.1 Document Owner
QQBP QA Manager

7.2 Reviewers
QQBP Head
QQBP QA Staff

7.3 Approver
QQBP

8.0 Policy and Program Documents

Directors Policy #10, Quality Assurance
1001 Fermilab Integrated Quality Assurance (IQA) Chapter 10, Suspect/Counterfeit Items
1006.1001 Controlling Suspect/Counterfeit Items Procedure
1006.1002 Suspect/Counterfeit Items QQBP Procedure
Fermilab Environment Safety & Health Manual (FESHM) Chapter 3010, Significant and Reportable Occurrences

9.0 Definitions

Counterfeit items are items whose documentation, appearance, performance, material, or other characteristics **are** knowingly misrepresented by the vendor, supplier, distributor, or manufacturer.

Nonconforming items are items that do not meet specified requirements.

Suspect items are items whose documentation, appearance, performance, material, or other characteristics **may have been** knowingly misrepresented by the vendor, supplier, distributor, or manufacturer.

Note: By definition, for an item to be considered S/CI officially it must first be nonconforming to specified requirements. Therefore all confirmed S/CI are nonconforming items but all nonconforming items are not necessarily S/CI.

10.0 References

DOE O 414.1C *Quality Assurance* – Contractor Requirements Document, Attachment 2 Section 4 – DOE-Wide Suspect/Counterfeit Item Prevention Process
DOE G 414.1-3- *Suspect Counterfeit Items Guide*

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Table of Revisions

Author	Description	Revision	Date
Jed Heyes	Final reconciliation and promotion	000 B	07/23/08
Jed Heyes	Updated to reference the role of the laboratory safety subcommittees. Clarified when response to OQBP notices are required	000 B1	0819/08
Jed Heyes, Kurt Mohr	Updated based on formatting comments from Business Services Section & Jeff Cotton, and for consistency with the S/CI Program	000 B2	11/07/08
Kurt Mohr	Changed Sect. 8 (Policy and Program) reference to "FIQMP" to "IQA"	000 B3	11/13/08
Kurt Mohr	Revised for consistency with SCI Program based on S/CI team review	000 B4	12/9/08
Kurt Mohr	Revised for consistency with S/CI Program, changes based on input from Joe Collins & Greg Mitchell	000 B5	12/10/08
Jed Heyes	Remove watermark. Minor edits for consistency with S/CI Program.	001	03/18/10